



The rise of evidence based public health in the European Union.

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The rise of evidence based public health in the European Union

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Abstract

Evidence-based medicine is most readily adopted when it can be applied to pharmaceutical or other clinical interventions for common diseases found in well-defined populations of patients. Public health policy on the other hand, is frequently formed in contentious, time-constrained circumstances where decisions are reached before the health problem and the population at risk are adequately defined. Policy may also emerge on the basis of an incomplete search for evidence and a limited assessment of the quality of research. Conducting trials of public health interventions is not usually possible in emerging disease situations such as a pandemic, where initially there are very small numbers of cases, speed of policy response appears critical and creating control groups for alternative interventions raises political problems. In respect of a problem such as illicit drug use, legal and ethical issues, populist politics and public opinion create significant barriers for evidence influenced public health policy. The paper examines the promotion of evidence based public health policies by the EU, using pandemic vaccination and responses to illicit drug use as cases.

Introduction

In examining the 'reach of Europeanization', the paper focuses on the role of the EU in promoting evidence based public health policies. This is an of potential 'added-value', which is a concept that is used to justify much EU policy action (Azzopardi-Muscat 2015) The paper examines two very different areas of health policy – pandemic response (with particular reference to the H1N1 episode in 2009) and responses to illicit drug misuse. One of the most obvious areas of value for EU health action is communicable disease and other cross-border threats to health. A border free Europe makes it easier for infectious diseases to spread yet it is widely accepted that EU action has been modest in its impact in dealing with this problem. This is in spite of the apparently strong evidence base that exists to support public health policy in this particular area. The reasoning behind using the EU as a driver for coordinated evidence-based policy action in respect of drug trafficking is equally compelling, but the related case of illicit drug misuse is rather more fragile, with

evidence also being of a different quality to that related to communicable diseases and pandemic in particular.

The intention is to examine the record and future potential of existing EU institutions in encouraging an evidence-based approach to health policy on the part of member states. Both illicit drugs and pandemic vaccination are mentioned in the key points summary of the EU health policy set out in *Together for Health* (Commission of the European Communities 2008). A separate European Drugs strategy was endorsed by the Justice and Home Affairs Council of the European Union during 2012-13 (ECMDDA 2016). The new 2013–20 strategy now incorporates the 'reduction of the health and social risks and harms caused by drugs' as a policy objective, alongside the better established drug policy aims of reducing supply and demand. The new strategy stresses the need for an empirical and evidence-based approach to drugs policy.

The analysis follows a basic premise that institutions and the use of evidence in policy are inextricably linked. In choosing policy areas where the use of evidence is affected by markedly different sets of problems and opportunities, the intention is to expose the strengths and weaknesses of the institutions of the EU with respect to promoting or enforcing evidence based policies.

The principle of subsidiarity is extremely important in the EU's historical relationship to health policy. While member states still have responsibility for the organization and delivery of health services and health care, Article 152 in the 1992 Maastricht Treaty, was seen as a key moment in signaling the EU's intentions to pursue a stronger role in public health policy. (Hunter pp.152-153) Health was increasingly defined as something broader than the prevention of disease, which had previously been the focus of the EU's policy. A period of institution building has followed during which DG SANCO (see below) was created in 1999 and began to establish itself as a dedicated health directorate. In September 2002 the European Parliament and the Council of Ministers adopted the DG SANCO's public health program. This reflected the broader view of public health now adopted. It focused on three strands of action: improving information and knowledge for the development of public health, responding rapidly to health threats and addressing health determinants. Some 16 years after Maastricht, *Together for Health* (Commission of the European Communities 2007), which is the basis of the EU's current position, is a broadly conceived strategy document, which identifies areas where EU countries cannot act

effectively alone and where cooperation at EU level is claimed to add value. Through a mixture of position taking, recommendations and encouragement to adopt principles, it addresses a comprehensive range of health policy issues including public health, health security, improving health systems through best practice in workforce planning, patient safety, pharmaceutical assessment, technology assessment and e-health issues. The strategy also indicates how the EU is involved with risk assessment through a number of associated scientific committees and forums that it funds for dialogue and collaboration. The document also records positions on taking action against diseases including anti-microbial resistance, communicable diseases, vaccinations, major diseases chronic diseases and rare diseases. The strategy indicates an intention to exert policy influence over 'health in society', which means addressing social determinants of health inequalities, ageing, healthy environments and screening and genetics. Fostering 'good health' signals an EU policy role in nutrition and physical activity, alcohol, Tobacco, illicit drugs, mental health and sexually transmitted disease. Also of some potential significance is the EU promotion of the production and use of health indicators and other data collection models.

Public health and EU institutions

In attempting to examine how well the EU performs in respect of promoting an evidence base in its strategic programme in public health, it is necessary to take full cognizance of the complex institutional structure involved. (Greer et al 2014)
Presented here is a brief summary of the roles played by key institutional actors operating within the EU complex.

European Commission

The European Commission, the 'executive branch' of the EU, is made up of individual Commissioners selected by each member state. The Commission initiates all EU legislation. The Commissioners are supported by Directorate Generals – DG's - which are broadly similar to a ministry in a member state. The main health actor is DG SANTE (formerly DG SANCO). DG SANTE (Health and Food safety), is responsible for health and health systems including public health. There is also a DG for Research and Innovation, which exerts a role in relation to bio-medical policy and DG Communication Networks, Content and Technology, which is engaged with IT and e-health. Of great significance to its potential as a driver for evidence-based

public health policy is the extent to which the Commission acts in a collective, consensus-based manner. Consensus is formed through discussions and agreements between DGs so-called 'interservice consultation', between the cabinets of the commissioners and through collective consideration by the College of Commissioners. The heavy emphasis on consensus-based decision making means that impacts on health policy may be of the lowest common denominator variety. This is highly significant in how evidence, regardless of its quality, which may not guarantee consensus, is treated in the EU complex.

In addition to initiating legislation the commission also influences policy through its publication of *Communications*. A recent example is the Communication – *On effective, accessible and resilient health systems* (European Commission 2014). This is a purely exhortative exercise, suggesting how health systems should be organised and what they should try and achieve, formulated in what are clearly conceived of as broad terms likely to command support across member states.

The European Parliament

Voters in the member states elect the Parliament. Parliament is organised in political groupings, which have a rough correspondence with the political parties back home in member state parliaments. The Parliament practices a form of decision-making, which has a reliance on collaboration and negotiation across the political groups. The Parliament is organised through 20 standing committees, which relate to major policy areas. In respect of health issues the lead committee is the Environment, Public Health and Food Safety Committee, although health research is actually the responsibility of another different committee the Industry, Research and Energy committee.

The traditional process of legislation also known as 'co-decision' begins with a Commission proposal. The proposal is considered by Parliament, which may amend it in first reading. An amended proposal will subsequently go to the Council of Ministers, which in turn may also make amendments in its first reading. If the Parliament and Council agree, then legislation will be passed. In the absence of agreement legislation will need to go through second readings in both the Parliament and Council. If they still cannot agree amendments made to the proposal, then a conciliation committee of MEPs and council representatives will try to seek to find a compromise that is acceptable to both Parliament and Council. Consensus is made

all the more significant in the legislative process, where it should be noted that while the Parliament operates on the basis of a majority decision, the arrangement in the Council is rather more complex. In some policy area a simple majority is sufficient but in others unanimity is required. Evidence may need to be almost incontrovertible before legislation would emerge from the EU on public health.

The Council of Ministers

This is the second legislative body and consists of member state health ministers who meet in Council. In total there are 10 policy specific 'sub-councils', each comprising representatives from the member states. Legislative proposals are taken through a majority voting system, although in practice it is normal for the President of the Council to seek broad consensus. Public health focused legislation would require the agreement of both the Parliament and the Council. The Council and the Parliament also produce 'political statements', which are not laws, but affirmations of priorities. Another unusual feature of the Council is seen in its capacity to issue recommendations, which unusually are legal acts with no legal mechanism for enforcement by member states. Examples include a recommendation on patient safety and health care associated infections and the 'European Code Against Cancer', a collection of recommended protocols on cancer screening and best practices for the prevention and treatment of cancers. Both political statements and recommendations are potentially of certain significance in the public health area, although actual examples few. In practice the availability of strong evidence that the Council can agree on may be elusive.

The European Council

The European Council consists of heads of government and effects a leadership position with respect to the direction of the EU. The European Council may also intervene to try and seek solutions to difficult to resolve issues. It has an elected President. With reference to illicit drugs, the Horizontal Working Party on Drugs (HDG) acts as the coordination body for drug-related issues. HDG develops all relevant legislation and political documents adopted by the Council including the EU drugs strategies and action plans. Since its creation in 1997 the HDG has been focused on drug supply reduction and drug demand reduction. Its role is based on coordination, international cooperation, and research, monitoring and evaluation.

Agencies

The EU supports a number of agencies, which have a health related role – the European Centre for Disease Control and Prevention (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the European Environment Agency (EEA) and the European Agency for Safety and Health at Work (EU-OSHA). Agencies are established by EU regulations and their role is directed to specific activities. The dominance of a market logic is often quite apparent in respect of the powers exerted by these agencies. For example EFSA and the EMA exert highly significant influence through control of access to the markets for relevant products. Conversely it seems that in the absence of a clear market logic, there is little prospect of agencies with specific rules in relation to vaccination policy or drugs misuse policy is being created.

Court of Justice.

EU law is directly applicable to member states, even if the member state has not 'transposed' acts into domestic legislation. It also has 'supremacy' in the sense that it overrides member state law. Were public health policy to be translated into a new law by the Parliament and European Council, then member states would have no option but to fall in line. The consequence of the 'direct effect' of EU law is that a private individual may enforce a right in EU law against their own state, or any part of it, or public body within it, such as national health care bodies. This enforcement happens within national courts. This has yet to materialise in respect of law relating to health systems. For example there are no significant examples of health policy impacting on health systems - the financing, accessibility and delivery of health services. Health and safety at work is a different matter with the EU very active in enforcement. Once again the dominant market logic is significant, since reaching specified health and safety standards is clearly a big factor in production costs and requires legal enforcement to provide a level playing field for business across the EU. (Hervey 2008)

New governance and ideational governance

Looking beyond the 'hard institutions' that comprise the EU complex is a form of politics that may have certain influence where consensus is a basic requirement for

action. (Hervey 2016) The terms 'new governance' and 'ideational governance' are used to describe the influence that is not exercised through organisational or legalistic channels. The related term ideational governance is also associated with other supranational bodies such as UN and NATO and describes a non-material influence of ideas on members, often exercised through networks and forums rather than organisational mechanisms - governing without government and 'soft law'. The new governance can be defined in terms of an increased participation of non-state actors, public/private collaboration, adaptability and constant learning and coordination. A range of activities are funded around the act of member state policy comparison, including benchmarking and extensive sponsorship of experts and networks. The EU Health Forum for example is promoted as a means of informing and involving key health stakeholders in European health policy. It disseminates information, launches ideas for debate and contributes to policy building. It has two components: the EU Health Policy Forum (52 non-governmental umbrella organisations) and the Open Forum. The Open Forum it is claimed, extends the work of the EU Health Policy Forum to a broader set of stakeholders through invitations to an annual flagship event, which is supposed to provide a platform for groups and organisations which are not normally part of the 'EU circuit'. The health policy forum brings together pan-European stakeholder organisations in the health sector at EU level to ensure that the EU's health strategy is open, transparent and responds to public concerns. It advises the Commission (and EU countries if appropriate) on health matters. (European Commission 2008)

Pandemic Vaccination and the EU

Vaccination represents an established and evidence proven intervention at both an individual and population level. It is an effective and unique proactive method for protecting the population against infectious diseases and it is estimated that immunizations avert close to 6 million deaths annually worldwide. The science behind vaccinations is well established. Vaccines are unique in how they are administered to a population of healthy, as opposed to diseased individuals to prevent rather than treat disease and offer the added benefit of herd immunity over other pharmaceuticals. In herd immunity, the chain of transmission of an infectious disease is disrupted by immunity of a sufficiently large proportion of a population, consequently individuals susceptible to the infectious disease will not get infected. The tradeoff is that individuals exposed to vaccines may never derive benefit from

exposure if they would not actually have become infected. This is significant since it represents a weakness in proving the effectiveness of vaccination on a purely individual basis. From a societal perspective, vaccination benefits include health benefits through a decrease in morbidity and mortality and economic benefits through a decrease in absence of work and are mediated through direct protection and herd immunity. (Lutjens, Dolk and Marnoch 2011)

A Commission statement from 2009 set out the strategic objectives to be pursued in relation to the coping with H1N1 in summary this included the following:

- Protect the integrity of the healthcare system and the country's critical infrastructure, i.e. maintain essential services;
 - Reduce morbidity and mortality, i.e. protect the vulnerable;
 - Reduce transmission of the pandemic virus within communities, i.e. limit the speed of spread of infection and limit the burden on the healthcare system.
- (Commission of the European Communities 2009)

On a pan-European level, the most important stakeholders in directing the pandemic influenza are the European Commission (EC), the European Medicines Agency (EMA, formerly EMeA), the ECDC (European Centre for Disease Control and Prevention) and committees cooperating with the EMA and ECDC. The EMA plays a key role in assessing and recommending authorization of pandemic vaccines for the European market.

It is unclear as to whether there were discussions within DG SANCO or elsewhere over the alternative interventions that could be used. For example mass-closures of public buildings such as schools and colleges. Vaccination was certainly the easiest intervention to pursue in political terms but even such a well-established intervention is not without controversy and as an intervention carrying potential benefits and risks it can be the subject of complex decision-making processes.

On 24 March 2009, an outbreak of novel H1N1 influenza A or swine flu, was identified in Mexico. The new virus quickly spread and on the 11th June 2009, the World Health Organization (WHO) raised the pandemic level to 6, indicating the first widespread influenza pandemic since the 1968 H3N2 Hong Kong flu. In line with an established protocol for action, the European Centre for Disease Prevention and Control (ECDC) and the WHO publicised clinical and pharmacological advisory

management guidelines for managing this pandemic. However European national authorities were responsible for developing national vaccination policies, which is perhaps surprising given the nature of the pandemic and its possible consequences for health.

Pandemic vaccinations and the evidence problem

In examining the response of member states to the H1N1 pandemic it is a relatively simple to examine data describing basic vaccination rates across the member states in the EU. This data refers to populations whose exposure to similar vaccines has been subject to large-scale clinical trials. This represents the part of the pandemic vaccination policy most easily based on highest quality of evidence. The record of member states having acted on evidence based EU recommendations is very hard to discern from the data. Out of the 27 member states 24 reported implementing pandemic vaccination programmes, Latvia and Poland had no programme and Bulgaria did not enact its programme because its supply of vaccine was not available until after the pandemic subsided. Some eight different vaccines were used, rather than just the three centrally authorised by the European Commission. The record is all the more uneven when vaccination target groups are examined. Twelve countries recommended vaccine for individuals of all ages, six countries had recommendations for varying age groups in children with three countries recommending pandemic vaccine to varying adult age groups. All 27 countries did recommend that health care workers be offered vaccine, with 16 countries recommending vaccine to all health care workers and 11 to selected categories. Vaccine was recommended for some other occupational categories such as the police in 12 countries.

Of the 24 countries with pandemic vaccination programmes, only two thirds of the countries had commenced their programmes by week 44 (end of week 1 November 2009), with a long 'tail' with some countries not able to start until near the end of 2009 due to capacity issues. The actual vaccination rates achieved varied considerably. Out of the 22 countries able to provide population-wide data on pandemic influenza vaccination, the coverage ranged from 0.4% to 59%. The highest reported population vaccination coverage was reached in the Netherlands and the Nordic countries - range 30% to 59%. Vaccination rates for health care workers were collected in 13 countries showing a range of 3% to 68%, with the highest coverage reported in the Netherlands, Romania and Hungary - range 50% to

68%).

Aside from the notably differing resource capacities to implement a vaccination programme of countries such as Bulgaria, Latvia and Poland in comparison with the rich northern European countries, there are political and societal factors, which explain differences in response to the vaccination advice issued by the EU. The VENICE group reported that countries were influenced by public perception factors that impacted negatively on vaccination rates. (VENICE 2012) Concerns about vaccine safety varied, as did belief in the value of vaccination. Particular fears were noted in half or more countries concerning the presence of thiomersal, adjuvants in the vaccine and the accelerated licensing process for the H1N1 vaccine. Vaccines containing the mercury-based preservative thiomersal were linked to the development of autism and other brain development disorders in a fraudulent research article published in 1998. An adjuvant is an ingredient of a vaccine that helps create a stronger immune response in the patient's body. Some vaccines made from weakened or dead germs contain naturally occurring adjuvants but most recent vaccines include just small components of germs, rather than the entire virus or bacteria. These vaccines use added adjuvants to ensure the body produces a good immune response. There are no grounds based on accepted research evidence to believe that adjuvants are dangerous, but as with thiomersal there are public fears over safety. In one member state, the Czech republic there had been an earlier vaccine contamination incident, which appears to have influenced the impact of the programme.

The data discussed above refers to groups whose exposure to vaccines has been the subject of extensive clinical trials. When detailed attention is paid to the vaccination of pregnant women an even less impressive record of EU influence emerges. The ECDC, following the advice given by WHO, recognized from the evidence of past epidemics and in seasonal influenza that pregnant women were along with people with chronic diseases and young children at high risk for complications from influenza. Vaccination of the pregnant woman would also protect the fetus, who could not be vaccinated. Illustrating the difficulty in finding incontrovertible evidence, the most recent pre-pandemic seasonal influenza vaccination advice issued by the ECDC had concluded that there is no consensus over whether pregnant women should be considered a risk group for (seasonal) influenza and "data are insufficient" for pregnant women to be considered a risk group at the EU level. (Nicol 2008)

There is also to be considered the long-standing reluctance to involve pregnant women in clinical trials due to fears of damage to the developing fetus. Consequently pregnant women are likely to find it harder to access thoroughly tested and approved medication including vaccinations. Similar to seasonal influenza (Nicoll 2008), the pandemic influenza vaccination decision-making process has been impaired by limited evidence, which was subject to multiple interpretations. Pregnancy is a unique group compared to other population groups in the sense it is a dynamic group that undergoes a number of phases. Each of the trimesters of pregnancy is subject to individual considerations with respect to vaccination of pregnancy. A study by Lutjens, Dolk and Marnoch (2011) based on responses from 20 countries found all had a policy of targeting pregnant women. For two of the four countries without official pandemic vaccination policies, some vaccination of pregnant women took place. In 12 out of 20 countries the policy was to vaccinate only second and third trimester pregnant women and in 8 out of 20 countries the policy was to vaccinate pregnant women regardless of trimester of pregnancy. Seven different vaccines were used for pregnant women, of which four contained adjuvants. Surprisingly given the nature of the issue, few countries had mechanisms to monitor the number of vaccinations given specifically to pregnant women over time. Vaccination uptake varied and as with the other population groups targeted differences in pandemic vaccination policy and practice might relate to variation in perception of vaccine efficacy and safety, operational issues related to vaccine manufacturing and procurement, and vaccination campaign systems. Comparing the Netherlands and the UK and their decisions on vaccinating pregnant women reveals the extent to which judgments about evidence were having to be made. As the pandemic spread, in September 2009 the Dutch revised their pandemic vaccination policy to include vaccination of 2nd and 3rd trimester healthy pregnant women, indicating that vaccination decisions had to be made with limited evidence initially as the risks to healthy pregnant women had been considered insufficient to warrant vaccination. In the UK, a country with a similar capacity to examine the same evidence, healthy pregnant women were considered to be at risk from the start of the pandemic outbreak.

Illicit Drug Misuse and the EU

In recent decades, the overall level of illicit drug use in Europe has grown rapidly. In the 21st century, the share of premature or avoidable mortality among young adults

that can be attributed to illicit drug overdose, accounts for an estimated 4% of deaths among those aged 15-39 in Europe. Deaths are often related to drug injecting and in most cases, involve a combination of substances. The number of problem opioid users in Europe is cautiously estimated by the EMCDDA (2011) at about 1.3 million. It is the opioid user population who are at most risk in terms of mortality related to illicit drug use. Such high levels of mortality among drug users has become a major policy issue for countries within the EU and in the late 1980s the European Parliament launched two investigatory commissions to examine different approaches towards illicit drugs, with a view to establishing a European policy. The results of both commissions made insufficient impact in the sense of establishing a common framing of the problem which remained a source of dispute between member states. In acknowledgement of the range of differing views on how to tackle illicit drugs, the principle of subsidiarity was invoked, meaning member states were at will to pursue their own policies. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) had already been set up in 1995, signifying the issue of illicit drug use was receiving EU attention. The first European Drugs strategy was agreed in 2000 (Chatwin 2012). In subsequent decades the issue has received a great deal of support from within the EU complex, but with little to show in terms of harmonization of policies across European member states. Differences in policy are still marked. Some countries treat drug users as 'diseased' and in need of help or in 'experimental phases' of their life and have consequently adopted a liberal approach, reflected in the minimising of contact with the criminal justice system experienced by users. At the other end of the spectrum there are countries which have adopted much harder approaches to drug use with an emphasis on the criminalisation of addicts. Chatwin (2011) draws attention to the difficulties in interpreting the impact of differing approaches to drug misuse in Europe. The cases of Sweden and the Netherlands are highly instructive in identifying why the EU has made little headway in promoting a common approach. In two countries that are in many ways very similar in terms of wealth, culture and values we find major divergences at every level. Chatwin describes Swedish drug policy as moralistic, aiming to eradicate rather than ameliorate impacts. The Dutch on the other hand pursue a policy that is more pragmatic and based on the concept of harm reduction. There appear to be consequences, Sweden has low rates of drug use but drug related deaths are three times the European average. In the Netherlands drug use is slightly above the average but the number of related deaths is low. There are grounds for arguing that the fairly extreme positions adopted by member states are not acceptable given the evidence that is available on the problem. Since the 1990s evidence has been

accumulated to support the conclusion that drug misuse treatment is effective in terms of reduced substance use; improvements in personal health and social functioning; and reduced public health and safety risks. However, the data collected is not always easy to use in the type of comparative research that might provide an evidence base for harmonization. Even a basic concept such as 'drug related death' may cause problems when different classifications used by member states become apparent. Drug treatments are difficult to conceptualise on a standardised basis. Interventions consist of specific change techniques, some of which directly address drug use, such as drug testing, drug counselling, and relapse prevention training, while others are directed at other problems, such as social skills training, family therapy or primary medical care. By contrast a vaccination is relatively easy to measure according to recognised standards. Some treatments have been extensively studied for their effectiveness, whereas others have received only limited attention. In all cases though context will vary considerably. There are often substantial differences in the nature of patients treated, while country specific capacities to offer treatments, their structures for intervention and the actual delivery methods render comparisons more or less worthless. Chatwin concludes there are no obvious relationships between the nature of drug policy and the size and nature of the drug problem.

Illicit drugs use and the evidence problem

A commitment to offering evidence-based treatment is a commendable aspiration and has obvious benefits in Europe, but in the absence of research evidence, decisions about the provision of treatment must be made according to criteria other than those of empirical research. The EU needs to confront specific problems encountered with collecting high quality evidence in this difficult area and the current European Drugs Strategy recognises the task involved in building policies on empirical evidence. (EMCDDA 2016) A UN (2002) review of the evidence base for drug abuse treatment discussed the research tools available including random controlled trials and uncontrolled observational evaluations (before and after studies) but also many far less robust methods. The differences in the quality of research notwithstanding, the UN concluded that there is strong evidence to show that both the detoxification-stabilization and rehabilitation-relapse prevention treatments are able to meet their stated goals and objectives and confer important benefits on patients, their families and the wider community and society. Tellingly this conclusion acknowledges that treatments benefits are framed in terms associated with that

specific intervention and can rarely be examined in the type of cost-benefit comparison with other treatments that might be likely to cause member state governments to adopt consistent treatment programmes. Decontextualizing treatments seems very difficult on the basis of the research tools employed. Illicit drug consumption habits are often very different even within one country. The differing criminal justice systems impact on the problem in a variety of ways. The availability of particular drugs and associated harm and crime effects will constantly change. The problem with evidence and policy also becomes markedly more complex when the problem is framed in a 'holistic' rather medical mode. There are no universal excepted criteria for success. For example what respective weight should be attached to reductions in individual user harm, deaths, associated criminal activities and nuisance when evaluating treatments? So-called controversial initiatives such as rooms where users can safely consume drugs and the official provision of heroin to users have very little pan- EU acceptance. The EU is designed to achieve compromises but in this policy area any common ground of significance seems to be elusive.

Evidence and institutions an appraisal.

Table 1 sets out general observations that can be made regarding the evidence relating to policy problems associated with pandemic vaccinations and responses to illicit drugs use. In spite of the difficulties noted in relation to pregnant women, it is nevertheless true that with the use of extensive high clinical trials and reference to historical data relating to vaccination make for a relatively high potential value. There are plenty of indications nevertheless that the EU could do far more to increase the scope and reliability of data collection in relation to pandemic vaccination. There is a big variation in the condition of data collected by member states and consequently 'medium' seems a fair classification. It is pertinent to ask whether a federal EU on the could organise a far more systematic data collection system, such as that available in the United States, where amongst other mechanisms, well-developed survey research is used. (CDCP 2013) In the event, the data discussed in this paper demonstrates a low actual use of evidence at the EU level. Member states were selective in their reference to evidence in formulating responses, as reflected in their heterogeneous vaccination response. Expert consensus on vaccinations and their efficacy and safety in use against pandemics is very high. Societal consensus on vaccination is fairly strong (medium), although scandals and scares have added a

greater fragility to the acceptance of vaccination and its benefits in certain countries. It could be argued that the wide social and cultural diversity found within the EU militates against imposing a common vaccination strategy on member states. Pandemics are episodic in character and the timeframe involved in responding to a pandemic vaccine is short. This undoubtedly also makes the assessment of evidence a less than fully rational exercise. Assumptions and shortcuts had to be made in 2009. The capacity of member states to act on evidence has been shown to be highly variable. In practice it is difficult to attribute coverage rates to opposition or lack of capacity and it is likely a mixture of both have influenced outcomes.

Table 1. Evidence and policy

| | Pandemic vaccination (H1N1) | Illicit drugs use |
|---|-----------------------------|-------------------|
| Potential opportunity and actual use (brackets) of evidence in policy | medium (low) | low (low) |
| Condition of evidence | medium | low |
| Societal consensus on evidence in member states | medium | low |
| Expert consensus on evidence | high | medium |
| Timeframe for policy | short | long |
| Member state capacity to act on evidence | varied | varied |

Illicit drugs present a different type of evidence problem in many respects. The potential to base policy on evidence is constrained by the lack of conceptual clarity related to, for example, definitions of both harm and criminal/nuisance effects. The quality of data collected reflects the fact that illicit drugs consumption is both illegal and stigmatized making it hard to accurately record behavioural patterns if there is a reliance on self-reporting. There is little agreement on the framing of policy issues. A long spectrum exists between the 'eradicators' and the 'pragmatics', with countries displaying various degrees of acceptance in between these positions depending on the exact issue. Politicians tend to aware of their need to reflect public opinion rather than lead on the issue of illicit drugs use. In these political and social circumstances there is low potential opportunity identified for the use of evidence based policy. The actual use is also low, with certain exceptions. The condition of evidence it is acknowledged needs to improve considerably, it is currently poor. The sheer range of treatments and other actions that are used undermines expert consensus on actions in relation to illicit drug misuse. Research methods are also numerous and lacking in

standardization. Consensus is accordingly rather less observable when compared to pandemic vaccination. Societal consensus even within one country is frequently difficult to pin down and should be classified as low when compared to the medium levels of agreement secured around vaccination. The timeframe for illicit drugs policy is long term. The problem has been around in various manifestations for a long time and shows no sign of disappearing. Member state capacity to act on evidence is very varied, which is partly a consequence of where a country sits on the eradication-pragmatism spectrum. Some countries have a capacity to offer some or all of the treatments used to engage with addiction, others would have very limited resources to offer anything. While, in the light of public fears over HIV, new member states are compelled to agree to offer needle exchange programmes and methadone substitution initiatives, their actual ability to comply can be questioned. Once again the problem of collecting reliable data makes compliance difficult to guarantee.

Table 2. EU power potential and actual (brackets)

| | Pandemic vaccination (H1N1) | Illicit drugs use |
|---------------------|-----------------------------|-------------------|
| Legislation | low (none) | low (none) |
| Market regulation | low (low) | none (none) |
| Agencies | medium (medium) | low (low) |
| New governance | high (low) | high (low) |
| Performance metrics | high (low) | high (low) |

Table 2 appraises the potential and actual impact of EU institutions to add value to pandemic vaccination and action on illicit drugs use. Legislative action seems highly unlikely in either area policy area examined now or in the immediate future. When the European Parliament and European Council agree then legislation is passed but policy evidence would have to be implausibly strong and compelling before legislation would emerge from the EU on public health. Market regulation is at the heart of the EU complex. The comparison between alcohol and tobacco is frequently cited as an indication of how market logic dominates policy. The EU will actively influence tobacco pricing on public health grounds but not alcohol, the reason being that members states are heavily involved in alcohol production but not at all in tobacco. It is conceivable that pandemic vaccination policy could be significantly influenced by rules relating to the manufacture of drugs, but this would be confined to specifications and licensing rather than coverage related harmonization, so legislative action potential has low potential. The record of vaccination use in the H1N1 pandemic suggests influence is low. Illicit drugs are by definition not part of the

market system regulated by the EU. It is difficult to even guess at how the EU could exert influence on the use of evidence-based policies in this area, so the potential for legislative action should be classified as 'none'. EU agencies are of much greater potential influence in the promotion of harmonized evidence based policy. Agencies are awarded considerable power in certain areas but always on the basis of a tightly constrained remit. In the field of health and safety at work EU-OSHA has a strong record. Contrastingly in the absence of a legislation-backed role to enforce evidence-based policies, in the two cases under examination, exhortation, best practice guides are relied on, with seemingly weak impacts to date. The two principle agencies in the cases examined are the EMCDDA (illicit drugs) and the ECDC (vaccines) and their central positions at the heart of expert communities in Europe are potentially of great significance to the promotion of evidence based policies, but advice they might provide is not translated into harmonization actions by the Commission. The ECDC can also be seen as a regional coordinating post, which linked with the WHO during the pandemic. In the case of pandemic vaccination, the H1N1 case demonstrated little impact beyond that fulfilled through a data collection and advisory role. The ECDC has demonstrated some success in promoting an evidence based approach to pandemics but could be only classed as a medium strength power of influence. The EMCDDA like the ECDC is in a strong position in a research network but must respect subsidiarity in a controversial policy area, where national differences are pronounced. Its power is consequently low in respect of promoting evidence based policy.

New governance or ideational governance is an important part of the contemporary EU complex. In both the case of pandemic vaccination and illicit drugs policy, the potential impact seems high given the commitment evident in the research communities to promoting best practices in respect of very serious public health problems. A question needs to be asked about the specific role played by the EU. Is it performing a pivotal role in the furtherance of research as implied by its sponsorship of numerous research and policy forums or alternately does it exploit work, which would be taking place anyway? Convincing researchers and other members of policy networks that evidence policies are desirable does not require the same political commitment as member state compliance with evidence. The current impact of new governance is disappointingly low in the two public health policy cases examined. New member states for example signed up to evidence supported policies on needles and methadone because this was part of the deal which gave them

membership. Providing a platform for experts to influence policy is a very passive and to date ineffective means of establishing evidence based policies in the EU.

Slightly more traditional in their intended mechanisms of influence than the discursive practices associated with EU sponsored forums, are the performance metrics systems being promoted as part of public health and drugs strategies. Performance metrics relating to aspects of vaccine coverage or drug addiction treatments may be potentially of high influence if they are used to regulate funding to member states or as part of a 'shaming scheme' which highlights poor performers. As yet this has not been realised and the impact appears low in the sense of influencing member states to comply with evidence based policy.

Conclusions

The paper has examined the 'reach of Europeanization', in the promoting of evidence based public health policies. In choosing policy areas where the use of evidence is affected by markedly different sets of problems and opportunities, the intention was to expose the strengths and weaknesses of the institutions of the EU. Existing EU institutions are clearly compromised in the extent to which they can promote evidence-based approaches to health policy on the part of member states. This is a discouraging finding given that institutions and the use of evidence in policy are inextricably linked. Evidence will rarely win a decision on its own, usually a certain level of institutional support is required. In the cases examined factors such as the condition of evidence and the varying levels of societal and expert consensus mean that considerable challenges face institutional promoters of evidence based policies. It is by no means clear that the EU complex is developing the means to establish evidence based public health. Institutional complexity, which is all too apparent when specific policy cases are examined, undermines the inherent power of well-researched evidence applied to complex policy issues.

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